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The role of regulatory agencies in public health emergencies: A critical review of global approaches and challenges

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Abstract

Regulatory agencies play a pivotal role in public health emergencies by ensuring that medical products, including vaccines, diagnostics, and therapeutics, are rapidly available while maintaining safety and efficacy standards. The COVID-19 pandemic, along with past crises such as the Ebola and Zika outbreaks, exposed both strengths and vulnerabilities in global regulatory frameworks. This paper critically reviews the role of regulatory agencies in public health emergencies, synthesizing existing literature to present new insights into their operational challenges and the reliance strategies employed to bridge capacity gaps. By examining case studies, such as the reliance on the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) by low- and middle-income countries (LMICs), this paper highlights the importance of global cooperation and reliance mechanisms in managing crises. Furthermore, it addresses challenges such as resource constraints, disparities in regulatory capacity, and ethical dilemmas faced when approving products based on limited data. The paper also explores the future direction of regulatory science, emphasizing the need for greater global regulatory convergence, capacity building, and the adoption of innovative digital tools. Ultimately, the paper argues that while reliance strategies are vital, long-term investment in national regulatory systems and global harmonization efforts are essential for a more equitable and effective response to future public health emergencies.

Keywords: Regulatory Agencies; Public Health Emergencies; Medical Products; Emergency Preparedness; Reliance; Vaccine Regulation; Accelerated Pathways; International Cooperation

1. Introduction

Public health emergencies (PHEs) have consistently challenged global health systems. Regulatory agencies are pivotal in dealing with these crises by guiding the development, approval, and distribution of medical products essential for mitigation efforts (Bolislis et al., 2021). Historically, events like the 2009 H1N1 pandemic (WHO, 2022), the Ebola virus outbreak, and most recently, the COVID-19 pandemic have exposed gaps in preparedness and response (WHO, 2022; Bolislis et al., 2021). These events underscore the urgency for efficient regulatory mechanisms to safeguard public health.

Regulatory agencies serve a dual purpose during emergencies: ensuring timely access to medical interventions while preserving public safety. The complexity of these responsibilities increases during PHEs due to the accelerated need for vaccines, diagnostics, and therapeutics, often with limited prior data. Agencies such as the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the World Health Organization (WHO) have taken central roles in these efforts, utilizing frameworks such as Emergency Use Authorizations (EUAs), fast-tracking procedures, and reliance on international regulatory decisions to streamline access to medical products (Saint-Raymond et al., 2022).

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During the COVID-19 pandemic, regulatory agencies adapted their protocols rapidly (Saint-Raymond et al., 2022). The FDA's issuance of EUAs for vaccines, treatments, and diagnostics, alongside the WHO's R&D Blueprint for global coordination, demonstrated a significant shift toward regulatory agility (Vaduganathan et al., 2020). This shift highlighted the essential role of international cooperation, with agencies worldwide adopting reliance strategies to expedite approvals and maintain safety standards (Broojerdi et al., 2021).

This paper explores the role of regulatory agencies in public health emergencies, synthesizing available literature to present a comprehensive understanding of their actions, challenges, and future opportunities. Through an analysis of key case studies and regulatory strategies, the paper aims to offer insights into how regulatory agencies can further optimize their roles in response to future health crises.

2. Methods

This study conducts a comprehensive review of secondary data to assess the role of regulatory agencies during public health emergencies. Using peer-reviewed journals reports from global health organizations, and case studies, the review identifies critical regulatory actions, challenges, and strategies implemented in response to various crises.

2.1. Study Design

The research employs a literature review approach, drawing from peer-reviewed articles, official reports, and regulatory frameworks. Data sources were selected based on their relevance to public health emergencies and their focus on regulatory interventions in managing medical products. The analysis synthesizes this existing body of knowledge to present new insights into the evolving role of regulatory agencies.

2.2. Data Sources

The primary sources of data include journal articles on regulatory preparedness and responses to health emergencies, documents from national regulatory authorities (NRAs), WHO reports, and key case studies of recent public health crises such as the COVID-19 pandemic and the Ebola outbreak (Bhavsar, Kim and Yu, 2010; Kieny and Rägo, 2016; Broojerdi et al., 2021). The selected literature represents a global perspective, with a focus on how reliance mechanisms, fast-track approvals, and international collaborations have influenced the management of medical products during emergencies.

2.3. Inclusion and Exclusion Criteria

The review focused on sources published within the past 15 years, capturing both the historical context and contemporary responses to public health emergencies. Studies detailing regulatory strategies such as Emergency Use Authorizations (EUAs), accelerated approval processes, and reliance mechanisms were prioritized. Excluded from the analysis were studies solely focused on epidemiological data without a regulatory perspective, as well as non-peer-reviewed sources.

2.4. Data Analysis

Data from the reviewed literature were synthesized thematically to identify common regulatory strategies, their implementation, and the challenges faced by agencies during public health emergencies. This thematic analysis allows for a clear understanding of the evolving role of regulatory bodies and presents an integrated view of how these institutions can improve future responses to emergencies (Broojerdi et al., 2021; Saint-Raymond et al., 2022).

3. Regulatory Agencies and Their Role in Public Health Emergencies

3.1. Defining the Role of Regulatory Agencies

Regulatory agencies act as gatekeepers in public health emergencies, overseeing the approval, distribution, and post-market surveillance of medical products. These institutions, including the FDA, EMA, and national regulatory authorities (NRAs) globally, are tasked with ensuring that vaccines, therapeutics, and diagnostics meet strict safety, efficacy, and quality standards before deployment (Bolislis et al., 2021). During emergencies, these responsibilities expand rapidly, forcing agencies to navigate uncharted territories where products often have limited data or lack conventional trial structures (Kieny and Rägo, 2016).

While their core role remains safeguarding public health, in a crisis, agencies must balance this with the urgent need to facilitate access to life-saving interventions. Regulatory agencies pivot to accelerated pathways, reliance on international evaluations, and even emergency-use authorizations, as demonstrated during the COVID-19 pandemic (Vaduganathan et al., 2020). The speed at which the FDA approved vaccines for COVID-19—utilizing the Emergency Use Authorization (EUA)—was unprecedented. This rapid approval process contrasts starkly with traditional approval timelines, reflecting the necessity for flexibility during PHEs (Broojerdi et al., 2021)

However, flexibility does not equate to compromised safety. Regulatory agencies employ robust oversight mechanisms post-authorization, such as pharmacovigilance systems to monitor adverse reactions and ensure ongoing safety (Vaduganathan et al., 2020). This dynamic regulatory approach, balancing urgency with oversight, underscores the evolving complexity of their role in emergencies.

3.2. Accelerated Regulatory Pathways

In public health emergencies, traditional regulatory pathways fall short of addressing the urgent need for interventions. To mitigate delays, regulatory agencies deploy several accelerated pathways. These include fast-track approvals, priority reviews, and conditional marketing authorizations, all aimed at expediting product access (Kieny and Rägo, 2016). The FDA's EUA mechanism exemplifies this, allowing unapproved medical products to be deployed based on the best available evidence when no adequate alternatives exist (Tran and Witek, 2021). Similarly, the EMA's Conditional Marketing Authorization (CMA) facilitates early access to promising medical products, requiring post-marketing obligations to ensure long-term safety.

While these pathways have proven effective in crises, they introduce risks. Fast-track processes inherently bypass standard procedures, sometimes relying on limited efficacy data or smaller trials (Broojerdi et al., 2021). The haste required for such approvals can lead to long-term complications, as seen in cases where vaccines or therapeutics require additional safety evaluations post-launch. Critically, the reliance on interim trial results—though necessary—demands greater post-market surveillance and pharmacovigilance systems to manage unforeseen risks (Alomar et al., 2020).

Despite these risks, the success of accelerated pathways in ensuring timely access to COVID-19 vaccines demonstrates their necessity in emergencies. A failure to expedite these approvals would have delayed life-saving interventions and cost countless lives. Nevertheless, this success highlights the need for continuous improvement in post-market oversight to close the safety gaps introduced by rapid approvals (Saint-Raymond et al., 2022).

3.3. Case Studies of Regulatory Responses

The COVID-19 pandemic revealed the strengths and vulnerabilities of global regulatory systems. The rapid development and approval of vaccines showcased the ability of regulatory agencies to adapt in unprecedented ways. For instance, the FDA's EUA for COVID-19 vaccines was a watershed moment in regulatory history, with approval timelines collapsing from years to months (Vaduganathan et al., 2020). Similarly, WHO's R&D Blueprint, launched in response to the Ebola crisis, played a vital role in coordinating vaccine research and development, proving that global collaboration is crucial during emergencies (WHO, 2016; Kieny and Rägo, 2016).

However, the response to Ebola highlighted the pitfalls of uncoordinated regulatory efforts. In regions heavily affected by the virus, the lack of a coherent regulatory framework delayed vaccine deployment (Bell et al., 2016). National agencies struggled to manage accelerated approvals, relying heavily on international partners like WHO and the FDA (Bell et al., 2016). This reliance, though effective, pointed to a systemic weakness in the regulatory infrastructure of low- and middle-income countries (LMICs), which are disproportionately affected by health emergencies (Broojerdi et al., 2021). These disparities emphasize the need for stronger global regulatory harmonization and capacity-building in resource-poor settings.

In contrast, the COVID-19 response demonstrated progress. LMICs, which had previously struggled with regulatory preparedness, benefitted from reliance mechanisms that allowed them to adopt decisions from established regulatory agencies (Saint-Raymond et al., 2022). This marked a significant improvement from the Ebola era and illustrated how collaborative regulatory approaches can close capacity gaps and enhance access to medical products in times of crisis.

4. Challenges Faced by Regulatory Agencies During Public Health Emergencies

4.1. Resource Constraints and Infrastructure

Regulatory agencies often encounter resource limitations during public health emergencies. These constraints are particularly acute in LMICs, where national regulatory authorities (NRAs) frequently lack the financial and human resources necessary to manage the influx of medical products requiring emergency approval (Broojerdi et al., 2021). In Nigeria, for instance, the National Agency for Food and Drug Administration and Control (NAFDAC) faced significant challenges during the early stages of the COVID-19 pandemic, struggling to expedite the approval of diagnostics and therapeutics due to insufficient staffing and technological infrastructure (NAFDAC, 2020). Reliance on external evaluations from agencies like the FDA and the EMA became necessary to bridge these gaps (NAFDAC, 2020; Saint-Raymond et al., 2022).

In contrast, agencies in high-income countries like the FDA or EMA, while better resourced, still face substantial operational strain during emergencies. The sheer volume of Emergency Use Authorization (EUA) applications during COVID-19 overwhelmed existing review frameworks, necessitating the temporary reallocation of resources and personnel from other essential regulatory functions (Vaduganathan et al., 2020) The regulatory infrastructure, even in well-developed systems, was stretched thin as these agencies managed both pandemic-related products and ongoing regulatory responsibilities for non-COVID-19 products (Vaduganathan et al., 2020).

4.2. Global Disparities in Regulatory Capacity

Regulatory preparedness is uneven across the globe, with stark differences between high-income and low-income countries. While the U.S. FDA and the European Medicines Agency (EMA) rapidly issued EUAs for COVID-19 vaccines, many LMICs struggled to align their national regulatory frameworks with these accelerated processes (Broojerdi et al., 2021). In Ghana, the Food and Drugs Authority (FDA) faced challenges in rapidly approving COVID-19 vaccines. Ghana eventually relied on decisions made by larger regulatory authorities like the WHO and the FDA (Owusu-Asante et al., 2022), highlighting a clear reliance on international collaboration due to its limited capacity for conducting independent evaluations (Saint-Raymond et al., 2022).

This reliance mechanism, while effective in providing quicker access to medical products, exposes a broader issue—most LMICs lack the regulatory autonomy to handle emergencies independently. These countries are often excluded from early clinical trial phases and are forced to depend on approvals made by NRAs from high-income countries. This system delays access to life-saving interventions and perpetuates global health inequalities, as countries with more advanced regulatory frameworks can move swiftly while others are left waiting (Saint-Raymond et al., 2022).

4.3. Navigating Ethical and Safety Concerns

Regulatory agencies face heightened ethical dilemmas during public health emergencies. The urgency to approve medical products conflicts with the rigorous safety and efficacy evaluations required under normal conditions (Saleh et al., 2021). The rush to provide access to vaccines and therapeutics during COVID-19 resulted in regulatory bodies approving products based on interim trial data, bypassing traditional, long-term studies (Saleh et al., 2021; (Vaduganathan et al., 2020). This was particularly evident with the approval of the AstraZeneca and Johnson & Johnson vaccines, where rare but serious adverse effects such as blood clots emerged post-authorization (Saleh et al., 2021).

The FDA and EMA, while responding quickly, had to navigate public scrutiny and media pressure. The rapid approval of vaccines raised questions about the balance between speed and safety. However, these agencies implemented robust post-market surveillance systems to track adverse events, demonstrating their commitment to public safety (Vaduganathan et al., 2020). Despite this, criticisms persisted, especially in LMICs, where these vaccines were deployed under less stringent monitoring environments. Without comparable pharmacovigilance systems in place, some countries were unable to manage the risks associated with accelerated approvals (Broojerdi et al., 2021).

4.4. Supply Chain and Logistical Challenges

In public health emergencies, supply chain disruptions add a layer of complexity for regulatory agencies (Okeagu et al., 2020). The COVID-19 pandemic severely impacted global supply chains, leading to shortages in raw materials and delays in the production of essential medical products (Okeagu et al., 2020). In response, regulatory agencies had to quickly adapt their frameworks to address the risk of counterfeit products flooding the market (Vaduganathan et al., 2020).

The FDA and WHO took active steps to prevent supply chain disruptions from compromising the quality of medical products. In March 2020, the FDA implemented temporary import flexibility measures to ensure continued access to medical supplies while still maintaining safety standards (Vaduganathan et al., 2020). However, in resource-poor settings like sub-Saharan Africa, regulatory agencies lacked the capacity to manage these disruptions. Nigeria's NAFDAC, for example, struggled to prevent the circulation of substandard and falsified medical products due to weak supply chain oversight and insufficient enforcement capacity (Saint-Raymond et al., 2022).

This contrast highlights the ongoing challenges that arise when global health emergencies intersect with pre-existing structural weaknesses. Regulatory agencies must therefore strengthen both domestic and global supply chains to ensure that quality medical products reach affected populations during crises.

5. Reliance and International Cooperation as Key Regulatory Strategies

5.1. The Concept of Reliance

Reliance, as defined by the WHO, refers to a process where one national regulatory authority uses the evaluations and decisions of another trusted NRA to expedite its regulatory processes (WHO, 2022). During public health emergencies, reliance mechanisms allow countries with limited regulatory capacity to benefit from the expertise and evaluations conducted by well-established regulatory bodies (Saint-Raymond et al., 2022). This concept was prominently applied during the COVID-19 pandemic, where countries like Kenya and South Africa relied on decisions made by the U.S. FDA and the EMA to approve vaccines and therapeutics (Broojerdi et al., 2021).

Regulatory reliance eliminates duplication, conserves resources, and ensures that medical products are deployed swiftly. The COVID-19 pandemic saw a significant increase in reliance mechanisms as LMICs sought to accelerate access to vaccines, diagnostics, and therapeutics without compromising safety Broojerdi et al., 2021. WHO's prequalification programs, which provide a global standard for the safety and efficacy of medical products, have become an essential tool in facilitating reliance during health crises (Kieny and Rägo, 2016).

5.2. Case Studies in Reliance

5.2.1. COVID-19 Vaccines in LMICs:

Several African nations, including Ghana and Kenya, exemplify the successful use of reliance mechanisms (Ayenigbara et al., 2021). Ghana's FDA relied heavily on assessments conducted by WHO and the EMA for its approval of the AstraZeneca and Pfizer COVID-19 vaccines (Ayenigbara et al., 2021; (Broojerdi et al., 2021). This approach not only expedited the approval process but also allowed Ghana to initiate its vaccination campaign in parallel with wealthier nations, ensuring earlier access to life-saving vaccines (Ayenigbara et al., 2021). Without reliance on external agencies, the country would have faced significant delays due to its limited regulatory infrastructure.

Kenya adopted a similar reliance approach, utilizing assessments from the EMA and WHO to approve COVID-19 vaccines (Ayenigbara et al., 2021. Reliance mechanisms proved vital in closing the regulatory capacity gap that could have delayed the national vaccination rollout((Saint-Raymond et al., 2022). These examples highlight how regulatory reliance ensures timely access to medical products while maintaining a high standard of safety.

5.2.2. Zika and Ebola Responses

During the Zika virus outbreak, Brazil's Agência Nacional de Vigilância Sanitária (ANVISA) utilized reliance strategies by collaborating with the U.S. FDA to expedite the approval of diagnostics and therapeutic tools. Similarly, in the Ebola crisis, reliance on WHO's Emergency Use Listing (EUL) procedure allowed West African nations to deploy experimental vaccines such as rVSV-ZEBOV without conducting full-scale independent evaluations (Kieny and Rägo, 2016). These reliance approaches ensured that regions with limited regulatory capacity were able to deploy interventions quickly and with confidence in their efficacy and safety.

These case studies demonstrate that reliance strategies not only streamline access to essential products but also foster collaboration and trust between regulatory agencies across different regions.

5.3. Harmonization and Global Regulatory Convergence

Reliance mechanisms are complemented by ongoing efforts to harmonize regulatory standards globally. Regulatory harmonization refers to the alignment of standards and processes across different jurisdictions, enabling smoother

collaboration between agencies during health emergencies (U.S FDA, 2019). WHO's Global Benchmarking Tool (GBT) has become instrumental in promoting harmonization by assessing and improving the maturity of national regulatory systems worldwide (Broojerdi et al., 2021). Through this tool, agencies can align their regulatory frameworks with global standards, facilitating reliance and collaboration during public health emergencies.

In Southeast Asia, the Association of Southeast Asian Nations (ASEAN) implemented the ASEAN Common Technical Dossier (ACTD), which harmonizes regulatory requirements for pharmaceutical products across member countries. This initiative proved invaluable during the COVID-19 pandemic, allowing member states to accelerate the review and approval of vaccines through shared regulatory assessments.

Similarly, the African Medicines Regulatory Harmonization (AMRH) initiative aims to standardize regulatory processes across African nations. By promoting reliance and harmonization, AMRH helps African countries manage the regulatory complexities of public health emergencies while maintaining quality control. These initiatives underscore the importance of global regulatory convergence in ensuring that all nations, regardless of capacity, can respond effectively to public health emergencies.

5.4. The Role of WHO in Global Regulatory Cooperation

WHO plays a pivotal role in facilitating international regulatory cooperation. Its Emergency Use Listing (EUL) procedure allows countries to approve vaccines and therapeutics during emergencies based on WHO's independent assessments (Kieny and Rägo, 2016). This was crucial during the COVID-19 pandemic, where WHO's EUL for vaccines enabled numerous LMICs to fast-track approvals and begin their vaccination campaigns. Additionally, WHO's regulatory prequalification programs ensure that critical medical products meet international safety and efficacy standards, promoting reliance among NRAs that cannot conduct comprehensive evaluations themselves (Saint-Raymond et al., 2022).

WHO also coordinates international regulatory platforms, such as the International Coalition of Medicines Regulatory Authorities (ICMRA), which brings together regulatory agencies worldwide to share data, assessments, and regulatory decisions during health emergencies. These collaborative platforms enhance transparency, reduce duplication, and ensure that all regulatory bodies are working from the same data sets, thus accelerating access to medical products on a global scale.

6. Policy Implications and Future Directions

6.1. Strengthening Global Regulatory Systems

The response to public health emergencies underscores the need to strengthen regulatory systems globally, particularly in LMICs. Reliance mechanisms, while effective in bridging capacity gaps, do not replace the need for robust national regulatory authorities (NRAs) that can independently assess medical products during emergencies. Governments must prioritize the allocation of resources to regulatory bodies, ensuring that these agencies are equipped with the infrastructure, expertise, and technology to manage future crises independently (Broojerdi et al., 2021; Saint-Raymond et al., 2022).

Capacity-building initiatives led by international organizations like WHO, through programs such as the Global Benchmarking Tool (GBT), must become central to global health policy. The disparities witnessed during the COVID-19 pandemic, where some countries were forced to wait for international approvals, highlight the importance of elevating national regulatory systems to a level where they can conduct independent evaluations (Saint-Raymond et al., 2022). Countries with mature regulatory systems such as the U.S. and Europe must commit to continued partnerships that emphasize knowledge transfer and resource-sharing with LMICs, ensuring a more equitable global response to future emergencies.

6.2. Promoting Reliance and Collaboration

Reliance has proven to be an indispensable tool during public health emergencies. However, for reliance to be more effective, global regulatory bodies must institutionalize this strategy beyond emergencies. Formalizing reliance mechanisms through legal and policy frameworks will ensure that regulatory cooperation becomes a default approach rather than an emergency measure (Saint-Raymond et al., 2022).

Governments must also work towards mutual recognition agreements that allow for seamless regulatory reliance, reducing the need for repeated evaluations across jurisdictions. The AMA and the ASEAN Harmonization initiatives have

demonstrated the potential for regional reliance to streamline access to medical products . These models should be expanded globally, ensuring that reliance mechanisms are recognized and employed across regions to facilitate faster access to life-saving interventions in future crises.

Furthermore, reliance mechanisms must include post-market surveillance protocols that ensure products approved through these expedited pathways are monitored effectively. This requires strengthening pharmacovigilance systems in countries that rely heavily on external approvals. Without adequate post-market monitoring, reliance could expose vulnerable populations to risks associated with unforeseen adverse effects, as seen during the AstraZeneca vaccine rollout (Tequare et al., 2021).

6.3. Research and Development of New Tools

The global response to the COVID-19 pandemic demonstrated the need for innovation in regulatory science. Regulatory agencies must prioritize research and development of new tools and frameworks that can handle the complexities of emerging health technologies during crises. The rapid development and deployment of mRNA vaccines during COVID-19 serve as a model for how regulatory innovation can accelerate access without sacrificing safety (Vaduganathan et al., 2020).

In particular, agencies need to invest in digital tools that streamline regulatory processes. Blockchain technology and artificial intelligence (AI) offer the potential for automating parts of the regulatory process, such as document verification and real-time safety monitoring, which could free up resources and improve efficiency (Kieny and Rägo, 2016). Digital platforms that facilitate data sharing between regulatory bodies, clinical trial sites and manufacturers must be scaled up to ensure that global regulators are working with real-time information during public health emergencies.

Furthermore, the development of rapid diagnostic and therapeutic assessment frameworks should be a priority. These frameworks should allow for iterative evaluations where products can be approved based on rolling data submissions, ensuring that promising interventions are deployed without waiting for full trial completion (Saint-Raymond et al., 2022). This would reduce the risk of delays and enable a more dynamic response to crises.

6.4. Enhancing Global Regulatory Convergence

The fragmented regulatory landscape exposed during COVID-19 revealed the need for greater global regulatory convergence. While reliance and collaboration played key roles in managing the pandemic, inconsistent regulatory standards across regions slowed down the approval and distribution of vaccines and therapeutics (Saint-Raymond et al., 2022). Global regulatory convergence—where NRAs harmonize their standards and processes—would eliminate these inefficiencies, creating a more unified response to future public health crises.

The International Council for Harmonisation (ICH) and WHO's ICMRA are examples of initiatives driving this convergence. Convergence should focus on standardizing clinical trial requirements, pharmacovigilance protocols, and regulatory timelines to ensure that products approved in one region can be swiftly deployed in others.

In addition to harmonization, the creation of global regulatory platforms where NRAs can share real-time data on clinical trials, product safety, and regulatory decisions would further enhance the efficiency of global responses to emergencies. WHO's prequalification program should be integrated into these platforms, ensuring that products meeting global safety and efficacy standards are available across all markets (Broojerdi et al., 2021).

7. Conclusion

Public health emergencies have laid bare both the strengths and weaknesses of global regulatory systems. Regulatory agencies play a pivotal role in ensuring that medical products are safe, effective, and available during crises, but the challenges they face are numerous and complex. The COVID-19 pandemic, along with previous health crises like the Ebola outbreak, demonstrated the necessity for regulatory flexibility, reliance on international evaluations, and global cooperation. Throughout these emergencies, reliance mechanisms emerged as one of the most powerful tools for countries with limited regulatory capacity, allowing them to benefit from the assessments of more established regulatory bodies. However, reliance must be viewed as a stepping stone toward building stronger national regulatory systems that are capable of responding independently to future crises. This requires sustained investment in infrastructure, expertise, and technological advancements, particularly in low- and middle-income countries.

Furthermore, the future of global regulatory preparedness lies in harmonization and convergence. The development of common regulatory standards, coupled with innovations in digital tools and real-time data-sharing platforms, can ensure that regulatory bodies across the world are aligned in their efforts to manage public health emergencies. Agencies must also continue to innovate, developing frameworks that allow for the rapid assessment and deployment of emerging health technologies without sacrificing safety or efficacy. The experiences drawn from past and present crises should shape the future of regulatory science. By strengthening global collaboration, promoting reliance, and advancing regulatory convergence, regulatory agencies can enhance their ability to protect public health and respond effectively to the inevitable challenges of future public health emergencies.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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